

Title 19 – MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30 – Division of Regulation and Licensure
PROPOSED REGULATIONS (May 11, 2010)

19 CSR 30-40.XXX STEMI Center Designation Requirements

PURPOSE: This rule establishes the requirements for participation in Missouri's STEMI center program.

PUBLISHER'S NOTE: The secretary of state has determined that the publication of the entire text of the material which is incorporated by reference as a portion of this rule would be unduly cumbersome and expensive. This material as incorporated by reference in this rule shall be maintained by the agency at its headquarters and shall be made available to the public for inspection and copying at no more than the actual cost of reproduction. This note applies only to the reference material. The entire text of the rule is printed here.

- (1) Participation in Missouri's STEMI center program is voluntary and no hospital shall be required to participate. No hospital shall in any way indicate to the public that it is a STEMI center unless that hospital has been designated as such by the department. Hospitals desiring STEMI center designation shall apply to the department. Only those hospitals found by review to be in compliance with the requirements of the rules in this chapter shall be designated by the department as STEMI centers.
- (2) The application required for STEMI center designation shall be made upon forms prepared or prescribed by the department and shall contain information the department deems necessary to make a fair determination of eligibility for review and designation in accordance with the rules of this chapter. The application for STEMI center designation shall be submitted to the department no less than sixty (60) days or no more than one hundred and twenty (120) days prior to the desired date of the initial designation, or expiration of the current designation.
 - (A) An application shall include the following information applicable for the designation level being requested: designation level requested; name, address, and telephone number of hospital; name of chief executive officer, chairman or president of board of trustees, STEMI medical director, STEMI program manager, medical director of emergency medicine, and medical director of intensive care and cardiac care unit; number of emergency department and hospital STEMI caseload, STEMI team activations, cardiac catheterization lab STEMI activations; computerized tomography (CT) scan capability, magnetic resonance imaging (MRI) capability, cardiovascular surgery capability or plan for surgical intervention; number of intensive care unit and cardiac care unit beds, cath lab suites, cardiac rehabilitation, cardiologists, interventional cardiologists, cardiothoracic surgeons, emergency department physicians, anesthesiologists, certified registered nurse anesthetists and anesthesiologist assistants; number of primary PCIs and elective PCIs; date of application; and signatures of the chairman or president of board of trustees, hospital chief executive officer, STEMI medical director, and director of emergency medicine. The STEMI center review and designation application form, included herein, is available at the Section for Health Standards and Licensure office, on-line at the department's website, or may be obtained by mailing a written request to Missouri Department of Health and Senior Services, Health Standards and Licensure, PO Box 570, Jefferson City, MO 65102-0570.
 - (B) The department shall notify the hospital of any apparent omissions or errors in the completion of the application and shall contact the hospital to arrange a date for the review.

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- (C) Failure of a hospital to cooperate in arranging for a mutually suitable date for review shall constitute forfeiture of application when a hospital's initial review is pending or suspension of designation when a hospital's verification or validation review is pending.
- (3) The review of hospitals for STEMI center designation shall include interviews with designated hospital staff, a review of the physical plant and equipment, and a review of records and documents as deemed necessary to assure compliance with the requirements of the rules of this chapter. The cost of any and all site reviews shall be paid by each applicant hospital or renewing STEMI center unless adequate funding is available to the department to pay for reviews.
 - (A) For the purpose of reviewing STEMI centers and hospitals applying for STEMI center designation, the department shall use review teams consisting of no more than (2) cardiologist/interventional cardiologist and one (1) emergency medicine physician who are experts in STEMI care and one (1) STEMI coordinator or STEMI program manager experienced in STEMI care. The team shall be disinterested politically and financially in the hospitals to be reviewed. Out-of-state review teams shall conduct levels I and II reviews. In-state reviewers may conduct level III and level IV reviews. In the event that out-of-state reviewers are unavailable, level II reviews may be conducted by in-state reviewers from EMS regions other than the region being reviewed with approval of the director of the department or his/her designee. When utilizing in-state review teams, the level II STEMI center shall have the right to refuse one (1) review team.
 - (B) Any substantial deficiencies cited in the initial review or the validation review regarding patient care issues, especially those related to delivery of timely intervention, shall require a focus review to be conducted. When deficiencies involve documentation, policy or equipment, the hospital's plan of correction shall be submitted to the department and verified by the department personnel.
 - (C) The verification review shall be conducted in the same manner and detail as initial and validation reviews. A review of the physical plant will not be necessary unless a deficiency was cited in the physical plant in the preceding initial or validation review. If deficiencies relate only to a limited number of areas of hospital operations, a focus review shall be conducted. The review team for a focus review shall be comprised of review team members with the required expertise to evaluate corrections in the specified deficiency area.
 - (D) Validation reviews shall occur every three (3) years.
 - (E) Upon completion of a review, the reviewers shall submit a report of their findings to the department. The report shall state whether the specific standards for STEMI center designation have or have not been met; if not met, in what way they were not met. The report shall include findings from the following: patient chart audits and a narrative summary to include pre-hospital, hospital, STEMI service, emergency department, operating room, recovery room, cardiac cath lab, clinical lab, intensive/cardiac care unit, cardiac rehabilitation, performance improvement and patient safety programs, education, outreach, research, chart review, and interviews. The department has final authority to determine compliance with the rules of this chapter.
 - (F) Within thirty (30) days after receiving a review report, the department shall return a copy of the report in whole to the chief executive officer of the hospital reviewed. Included with the report shall be notification indicating that the hospital has met the criteria for STEMI center designation or has failed to meet the criteria for the designation level for which it applied and options the hospital may pursue.

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- (G) If a verification or focus review is required, the hospital shall be allowed a period of six (6) months to correct deficiencies. A plan of correction form shall be provided to the department and shall be completed by the hospital and returned to the department within thirty (30) days after notification of review findings.
 - (H) Once a review is completed, a final report shall be prepared by the department. The final report shall be public record and shall disclose the standards by which the reviews were conducted and whether the standards were met. The reports filed by the reviewers shall be held confidential and shall be disclosed only to the hospital's chief executive officer or an authorized representative.
- (4) STEMI center designation shall be valid for a period of three (3) years from the date the STEMI center is designated. Expiration of the designation shall occur unless the STEMI center applies for validation review within this three (3)-year period.
- (A) STEMI center designation shall be site specific and not transferable when a STEMI center changes location.
 - (B) Once designated as a STEMI center, a hospital may voluntarily surrender the designation at any time without giving cause, by contacting the department. In these cases, the application and review process shall be completed again before the designation may be reinstated.
- (5) The department shall have the authority to put on probation, suspend, revoke, or deny STEMI center designation if there is reasonable cause to believe that there has been a substantial failure to comply with the requirements of the rules in this chapter.
- (A) The department shall investigate complaints and lower than average performance and outcomes of STEMI centers.
 - (B) Failure of the hospital to cooperate in providing documentation and interviews with appropriate staff may result in revocation of STEMI center designation.
 - (C) Any hospital, which takes adverse action toward an employee for cooperating with the department regarding a complaint or performance issue, is subject to revocation of STEMI center designation